

## II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

### 2.1. General Information Establishment

- 510(k): K072905
- Manufacturer: **NEUERO ENGINEERING INC.**
- Address: 20F, No. 171, Cheng-Kuang Rd.,  
San-Chung City, 24160, Taipei County, Taiwan
- Registration Number: 3004512547
- Contact Person: Dr. Ke-Min Jen  
Official Correspondent  
886-3-5208829 (Tel)  
886-3-5209783 (Fax)
- Date Submitted: October 1, 2007

### Device

- **Proprietary Name:** *3test<sup>®</sup> Supreme Glucose Monitoring System*
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, OVER  
THE COUNTER, Class II
- **Product Code:** NBW

### 2.2. Safety and Effectiveness Information

- **Predicate Device:**  
Claim of Substantial Equivalence (SE) is made to NEUERO ENGINEERING INC.  
-- *3test<sup>®</sup> Blood Glucose Monitoring System ( K050224 )*.
- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, *3test<sup>®</sup> Supreme Glucose Monitoring System* only needs a small amount of blood ( 2μL, same as predicate device ). Capillary action at the

end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in **5** seconds, and **200** blood glucose result memory.

- **Intended Use:**

The *3test<sup>®</sup> Supreme Glucose Test Strip* is intended to measure the glucose in whole blood with the *3test<sup>®</sup> Supreme Glucose Monitoring System*. It is suitable for a person with diabetes to monitor their blood glucose at home by themselves. The *3test<sup>®</sup> Supreme Glucose Monitoring System* can also be used at clinical sites by nurses or professional people to test patient's glucose level in whole blood.

- **Synopsis of Test Methods and Results**

Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

- **Substantial Equivalence (SE)**

A claim of substantial equivalence is made to the predicate device NEUERO ENGINEERING INC. -- *3test<sup>®</sup> Blood Glucose Monitoring System ( K050224 )*. Both of them used with the same test strips, have the same working principle and technologies. The differences are the levels range of the control solution, battery number, the memory results, and test Strip lot calibration. There are no safety and effectiveness aspects arising from the subject device. They are substantially equivalent.



Dr. Jen, Ke-Min  
Official Correspondent for  
NEUERO ENGINEERING INC.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
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c/o Dr. Ke-Min Jen  
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San-Chung City, Taipei County  
241 Taiwan, ROC

**APR 18 2008**

Re: k072905  
Trade Name: 3test Supreme Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose Monitoring System  
Regulatory Class: Class II  
Product Codes: NBW, CGA  
Dated: April 2, 2008  
Received: April 7, 2008

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): k072905

Device Name: 3test Supreme Glucose Monitoring System

Indication For Use:

The 3test® Glucose Supreme Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.

Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use   X    
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

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